UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: JOHNSON & JOHNSON DERIVATIVE LITIGATION This Document Relates To: All Actions.	Civil Action No. 10-2033 (FLW)(DEA)

LEAD PLAINTIFFS' SUR-REPLY IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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I. Preliminary Statement

The Complaint alleges in detail that for more than 7 years, the J&J Board consciously ignored, if not actively encouraged: (i) the illegal promotion of numerous drugs and devices for uses that were not approved by the FDA, including by paying tens of millions of dollars in kickbacks; and (ii) illegal drug manufacturing processes, which harmed consumers and led to unprecedented recalls. (Pl. Opp. 11-20.) Plaintiffs Opposition to the Motion to Dismiss made clear that Defendants, unable to confront the allegations of the Complaint directly, chose instead to set up and knock down a series of "straw man" allegations.

Unable to deny they received direct red flags, Defendants change tact in their Reply Brief. In effect conceding that their motion fails, Defendants present new arguments based on their view of new facts outside the four corners of the Complaint. However, Defendants' new version of events is squarely at odds with the detailed allegations of widespread, systemic misconduct alleged in the Complaint. (Reply at 3)[1] Besides raising factual issues defeating the pending Motion, the Reply Brief reflects precisely the same attitude towards pervasive violations of drug manufacturing and marketing laws alleged in the Complaint that has put J&J at risk and run its reputation into the ground. ¶¶86-90, 105-121.

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[1] The Court should disregard the Individual Defendants' improper reply brief, which circumvented the Court's April 20, 2011 Order.

The fallout from the Board's breaches continues. Seemingly every other week, J&J announces yet another recall, product problem, reorganization of a troubled "flagship" division, or settlement of criminal charges. In fact, J&J has announced three more massive recalls – covering prescription drugs, OTC drugs and medical devices – just since the filing of the Opposition on March 21, 2011. (Cecchi Decl., Exs. A-F). J&J remains at grave risk. The Court should deny Defendants' motion and allow discovery to begin immediately.

II. Defendants' Arguments Are Procedurally Improper and Wrong

A. J&J's Egregious Misconduct Is Plainly Material to the Business

Even today, Defendants deny the scope of J&J's problems. Defendants argue the Complaint "alleges misconduct at 3 percent – 8 of 250 – of J&J's operating companies," the marketing misconduct "involved just two of the hundreds of medical devices sold by J&J subsidiaries, and just three of J&J's many pharmaceutical drugs," and the manufacturing misconduct involved "just two of the company's 139 worldwide manufacturing facilities." (Reply at 9). Defendants' argument ignores the well-pleaded allegations of the Complaint and is factually disingenuous.

First, the operating divisions discussed in the Complaint generated billions of dollars in revenues during the relevant period (unlike the hundreds of corporate shells

Defendants refer to).[2] ¶¶52, 84-85. The illegally promoted drugs and medical devices were among J&J's most important products.[3] ¶¶47-48. Just as was the case in *In re SFBC Int'l., Inc. Sec. & Deriv. Litig.*, "the alleged misconduct related to the core of [the company's] business." 495 F. Supp. 2d 477, 486 (D.N.J. 2007) (distinguishing *In re Caremark In'l.,* 698 A.2d 959 (Del. Ch. 1996)).

Second, the manufacturing facilities at Fort Washington and Las Piedras were material enough to J&J that the lack of control over those plants caused the unprecedented recalls of Motrin, Tylenol, Benadryl, Rolaids, Simply Sleep, and St. Joseph Aspirin, many of which are continuing today. ¶¶84-158. The FDA warned in 2004 that J&J's manufacturing processes violated cGMP, yet Defendants did nothing to remedy the defects. ¶¶86-90, 113-121. In December 2010, the FDA warned that J&J had still not corrected the defects. ¶¶111-121. Defendants' suggestion that J&J has suffered mere "discrete issues" beneath the Board's purview is mindboggling. *See In re Tower Air, Inc.*, 416 F.3d 229, 239 (3d Cir. 2005) ("Lives are on the line … We

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[2] For example, the DePuy, Cordis and Vision Care divisions generated $66 billion in revenues between 2003 and 2009, including from the illegal promotion of biliary stents and hip and knee replacements. ¶¶51-52. The McNeil consumer healthcare division manufactured and distributed Tylenol –a critical J&J product. ¶¶84-85.

[3] For example, Risperdal generated $23.6 billion in revenues between 2003 and 2009. During this time, Topamax generated another $12.5 billion while the Board knew that 8 out of every 10 prescriptions in the U.S. were off label. ¶¶50, 167, 202.

can imagine few things more egregious. The officers' alleged passivity in the face of negative maintenance reports seems so far beyond the bounds of reasonable business judgment that its only explanation is bad faith").

B. Defendants Harmed J&J by Ignoring Timely Red Flags

According to Defendants, "the Board did not receive any alleged red flags for most of the alleged misconduct until after the conduct had already ended." (Reply at 12). Defendants say they should not be held liable unless they failed to respond after red flags were received. (Reply at 14). Defendants' arguments are factually inconsistent with the allegations of the Complaint.[4] Indeed, the Complaint details at least seven years of red flags demonstrating remarkably similar illegal promotion practices, continuing across multiple subsidiaries and business segments and affecting major drugs and medical devices. ¶¶165, 177-183, 185-91, 195-99, 202-06, 215-25, 231-38, 242-52, 269-74. As alleged in the Complaint, at least a majority of the Board had specific knowledge of explicit red flags and permitted the illegal practices to continue. ¶¶17, 202, 279, 281. The same is true for manufacturing processes

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[4] Contrary to Defendants' argument, the Complaint alleges that the illegal promotion of Risperal continued through 2008 – not 2002. Compare Reply at 13 with ¶¶183, 190-91. Likewise, the illegal promotion of Topamax did not end in 2003 but rather continued at least through 2007. *See* Reply at 13 and ¶¶202, 203, 205. The illegal promotion oof Natrecor did not end in July 2005 (Reply at 13), but rather ended in March 2006. ¶¶237-38. Even then, it only ended because the federal healthcare programs barred all payments for the off label use that J&J was pushing. *Id.*

violating cGMP. ¶¶86-90, 111-121. Defendants' suggestion that red flags with respect to one product or plant, or off-label promotion of one blockbuster drug, are irrelevant for other products or plants, or the same off-label promotion of other major drugs, does little more than underscore the validity of the FDA's concern in 2004, that the Company only engaged in "specific spot fixes" while refusing to "take a systematic approach to comprehensively cover the corrections." (Pl. Opp. at 4.) Defendants' attempt to distinguish *SFBC, In re Pfizer, Inc. S'holder Deriv. Litig.*, 722 F. Supp. 2d 453 (S.D.N.Y. 2010) and *In re Abbott Labs Deriv. S'holders Litig.*, 325 F. 3d 795 (7th Cir. 2003) fails for this reason alone.

III. Defendants' Arguments for a Stay Are Unfounded

According to Defendants, the Court should stay this action because "[t]he rationales for a stay apply regardless of the Committee's mandate." (Reply at 23.) Defendants cite no authority for staying an action to allow a powerless committee to investigate serious allegations of Board misconduct, and fail to distinguish Plaintiffs' cases holding to the contrary. (Pl. Opp. at 44-45.) Moreover, if the Court agrees the Complaint adequately alleges demand was futile, a majority of the Special Committee is conflicted and there is no basis to stay this action in any event.

Based on the foregoing, and on Plaintiffs' opposition brief filed on March 21, 2011, the Court should deny Defendants' motion to dismiss.

DATED: May 2, 2011

Respectfully submitted,

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